

REMARKS AND ARGUMENTS

Claims 1, 3 and 7-15 are pending in the present application, of which claims 1, 9 and 10 are independent. No changes to the claims have been made in the present Response.

Claims 1, 3 and 7-12 were rejected under 35 U.S.C. § 103(a) as unpatentable over Antoni-Zimmerman et al. Applicants respectfully traverse this rejection.

Applicants have argued in their responses to the earlier Office Actions that a finding of obviousness may be rebutted by demonstrating unexpected results relative to the prior art disclosure (*See* M.P.E.P. § 2144.05(III)), and that Applicants have demonstrated (see pages 10-21) that the claimed biocide combinations display synergistic activity (synergy index < 1) within the claimed ranges of biocide ratios. The Declaration of Eileen F. Warwick, submitted January 23, 2009, is now of record in this case, as acknowledged in the Office Action. A second Declaration has been submitted with this Response. The declarant states that the existence of synergy between any pair of biocides, and also the range of biocide ratios over which it occurs, could not have been predicted. The cited reference does nothing to lead one to expect Applicants' claimed results. The only synergistic interaction disclosed by Antoni-Zimmerman et al. is between 2-methyl-3-isothiazolone ("MI") and 1,2-benzisothiazolone. While a long list of additional biocides is provided, some of which are combined with MI in the present claims, there is no suggestion in the reference that any of the listed biocides would produce a synergistic combination with MI. The lack of specific disclosure in the reference, coupled with the declarant's statement that any particular synergistic interaction could not have been expected, make it clear that the synergy discovered by Applicants could not be obvious over the reference. The Office appears to question the validity of declarant's statement, and in so doing gives more weight to its own evaluation than to that of an expert. The statement of an expert "in this field is entitled to more weight than that of a layman" and by not accepting Declarant's statements, the Office has "erroneously substituted its judgment for that of an established expert in the art." *In re Zeidler*, 682 F.2d 961, 966-7 (C.C.P.A. 1982); *see also*, *In re Neave*, 370 F.2d 961 (C.C.P.A. 1967), *Ex parte Ridyard*, 2001 Pat. App. LEXIS 132 (B.P.A.I. 2001).

The Office Action appears to rely on *Ex parte Quadranti* to argue that synergy is never unexpected. However, there are important differences between the factual situation in that case and in the present application. In *Quadranti*, the Board objected to the Colby equation used to demonstrate synergy, stating that it was not considered valid by workers in the field. *Quadranti*, 1992 Pat. App. LEXIS 26, *2-*3. Here, Applicants are relying on the Synergy Index (SI) described by Kull, F.C.; Eisman, P.C.; Sylwestrowicz, H.D. and Mayer, R.L., in Applied Microbiology

9:538-541 (1961), an accepted method for determining synergy, as stated on page 9 of the present application.

The Board in *Quadranti* also objected to the fact that the data presented did not show very good effectiveness. *Id.* at *5. In the present application, the SI values are calculated from minimum inhibitory concentration (MIC) of each component, which “is the concentration tested under a specific set of conditions that prevents the growth of added microorganisms” (see page 9, lines 19-20). Therefore, each SI represents a combination of biocides that actually prevents growth of microorganisms.

Applicants have made these arguments with regard to *Ex parte Quadranti* previously, and yet none of the Office Actions specifically addresses Applicants’ arguments. The current Office Action contains only lengthy quotes from the case with no analysis to support the apparent assertion that synergy should have been expected. Likewise, the Office Action does not address the statements made by declarant regarding the unexpectedness of synergistic interactions. The Office Action merely reiterates earlier statements that MI displays synergy with some particular biocides, as shown in the reference, but ignores declarant’s statement that the claimed synergistic interactions between MI and other biocides could not have been predicted. “Office personnel should avoid giving evidence no weight.” M.P.E.P. § 2145; *see also In re Zeidler* and other cases cited above.

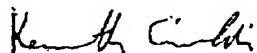
The Office Action also includes quotes attributed to other cases, including *KSR* and *Brenner*, but without showing how these cases relate to the present application. The quotes attributed to *Brenner* are particularly puzzling. They include the statement that “patent protection is granted in return for an enabling disclosure of an invention, not for vague limitations of general ideas that may or may not be workable.” Office Action at page 17. Applicants have claimed a specific invention whose enabling disclosure has not been questioned and they have shown that the claimed combinations in fact inhibit growth of microorganisms better than the individual biocides. Therefore, there is nothing “vague” or “general” or “not ... workable” about the present claims or specification.

As for *KSR*, the Supreme Court stated that the “combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l v. Teleflex*, 127 S. Ct. 1727, 1739 (2007) (emphasis added). In the present application, known biocides were combined, but the combination did not yield predictable results, as attested to in the Declaration filed on January 23. Accordingly, *KSR* cannot be relied on with regard to the present application. The Federal Circuit rejected the application of *KSR* in cases with a showing of unpredictable results in *Sanofi-Synthelabo v. Apotex*, 550 F.3d 1075 (Fed. Cir. 2008). In that case, the patentee isolated one enantiomer of a known racemic drug and obtained an unpredictable result. The Federal Circuit quoted the passage cited above from *KSR* and held that “the result of this

separation of enantiomers was unpredictable" and that accordingly "the principles of KSR do not affect the conclusion herein." 550 F.3d at 1090. In the present application, the biocide combinations also did not yield predictable results. In some cases, different patterns of synergy were observed for different biocides, and the ranges over which synergy was observed also were not predictable, as stated in the Declaration submitted previously. The result in *Sanofi-Synthelabo* is equally applicable to this case and requires that *KSR* does not apply when unpredictable results are obtained.

Applicants believe that the foregoing arguments have overcome the rejection. However, if the Examiner has any further objections to the application, Applicants respectfully request that the Examiner contact Applicants' undersigned attorney by telephone at (847) 649-3891 to discuss the remaining issues.

Respectfully submitted,



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